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10/565,414	01/23/2006	Joel M. Kauffman	ESSR:103US/10600581	6229
	7590 03/02/200 & JAWORSKI L.L.P.	EXAMINER		
600 CONGRES		SHTERENGARTS, SAMANTHA L		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Comments	10/565,414	KAUFFMAN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Samantha L. Shterengarts	1626				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 15 De	ecember 2008.					
·— · · · · · · · · · · · · · · · · · ·	action is non-final.					
	/ 					
,—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-10 and 12-21</u> is/are pending in the application.						
4a) Of the above claim(s) <u>9,10,12-19 and 21</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-3,6,8 and 20</u> is/are rejected.						
7)⊠ Claim(s) <u>4.5 and 7</u> is/are objected to.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 22 Jan 07.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite				

DETAILED ACTION

Priority

1. The instant application is a national stage entry of PCT/EP05/14202, filed December 30, 2005.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on January 22, 2007 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS document was considered. A signed copy of form 1449 is enclosed herewith.

Election/Restrictions

3. Applicant's election with traverse of Group I in the reply filed on December 15, 2008 is acknowledged. The traversal is on the ground(s) that the restriction requirement does not rely on any prior art document which would confirm that a special technical feature does not exist between Groups I, II, III, and IV. This is not found persuasive for the following reasons.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a)

Where a group of inventions is claimed in an application, the requirement of unity of

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invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. A special technical feature is the only non-variable core that is common to all compounds of the formulae in instant claim 1.

There is no non-variable core among the three formulae of instant claim 1, and therefore, there is no special technical feature that relates to all inventions of the application. The special technical feature of Group II, claims 9-10, is the combination of the polymer blend and the compounds of instant claim 1. The special technical feature of Group III, claims 12-13, is the step of molding the polymer blend into a desired shape to produce an optical lens. The special technical feature of Group IV, claims 14-16, is the combination of the organic glass substrate and the compounds of instant claim 1. The special technical feature of Group V, claims 17-19 and new claim 21 is the step of reacting an intermediate compound of the first formula in claim 17 with the second formula in claim 17, neither of which are special technical features of any of the other groups of the instant invention.

Furthermore, even if it could be argued that there is a special technical feature which is a non-variable core among the compounds of instant claim 1, it would be the following structure:

This is the only non-variable core in any of the formulae from instant claim 1. This core technical feature is not a special technical feature because it fails to define a

contribution over the prior art as can be seen in Belfield et al., which discloses the same core as the second formula in instant Claim 1.

Therefore, claims 1-10 and 12-21 are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature as the technical feature present fails to define a contribution over the prior art. The core technical feature that is being claimed is taught by the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Furthermore, in regards to Groups I-V, even if unity of invention under 37 CFR 1.475(a) is not considered lacking, which it is as evidenced above, unity is lacking under 37 CFR 1.475(b). Under 37 CFR 1.475(b): A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specifically designed for carrying out the said process.

And according to 37 CFR 1.475(c): if an application contains claims to more or less than

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one of the combinations of categories of invention set forth in paragraph 37 CFR 1.475(b), unity of invention might not be present.

Therefore, since the claims are drawn to various products of the formulae of claim 1 (Groups I, II, and IV) and various methods of using products of the formula of claim 1 (Groups III and V), and according to 37 CFR 1.475(e): the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claims.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical feature, the claims lack unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

4. As per MPEP 803.02, the Examiner will determine whether the entire scope of the claims is patentable. Applicants' elected species makes a contribution over the prior art of record. Therefore, according to MPEP 803.02: should the elected species appear allowable, the search of the Markush-type claim will be extended. If the search is extended and a non-elected species is not found allowable, the Markush-type claim shall be rejected and claimed to the nonelected invention held withdrawn from further consideration. The search of the Markush-type claim has been extended to include the products of all formulae of instant claim 1. It has been determined that the entire scope claimed is not patentable.

Status of the Claims

5. Currently, Claims 1-10 and 12-21 are pending in the instant application. Claims 9-10, 12-19, and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being

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drawn to a non-elected invention. Claims 1-8 and 20, read on an elected invention and are therefore under consideration in the instant application.

Claim Objections

6. Claims 2, 4, 5, and 7 are objected to because of the following informalities: Claims 2, 4, 5, and 7 do not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, 6, 8, and 20 are rejected under 35 U.S.C. 112 1st paragraph as failing to comply with the written description requirement.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor has possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 10081 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398*.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus.

MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad genus. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically state that for each claim drawn to a genus the written description requirement may be satisfied through sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to drawings or structural chemical formulas; c)

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disclosure of relevant, identifying characteristics (i.e. structure) by functional characteristics

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coupled with a known or disclosed correlation between function and structure. The analysis of

whether the specification complies with the written description requirement calls for the

examiner to compare the scope of the claim with the scope of the description to determine

whether applicant has demonstrated possession of the claimed invention (Federal Register, Vol.

66, No. 4, p. 1105, 3rd column, 3rd paragraph). Below is such a comparison.

I. Scope of Claims

Compounds of the formulae of instant claim 1:

The variables X¹, X², Y, R², R³, R¹², R¹³, R²², and R²³. are claimed *broader* than

what is supported by the disclosure (see section II below).

II. Scope of Disclosure

Reduction to Practice:

The compounds reduced to practice support the following substituents for the

aforementioned variables (and their obvious variants):

 $X^1 = S \text{ or } O$

 $X^2 = S$ or O

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 R^2 and R^3 =

 R^{12} and R^{13} = methyl or homologue ethyl

 R^{22} and R^{23} = methyl or homologue ethyl

Reduction to Structure or Chemical Formulas

The only disclosure, in addition to the species reduced to practice, is in the form of <u>lists</u> of possible substituents for X¹, X², Y, R², R³, R¹², R¹³, R²², and R²³. This type of disclosure is not viewed to be a representation of any of the species it encompasses. A "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. MPEP 2163.I.A. and *Fujikawa v. Wattanasin*, 93 F. 3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Therefore, there is no disclosure of species (e.g. by reduction to structural/chemical formulae) in addition to those reduced to practice.

The embodiments of the instant invention as exemplified on pages 12-25 of the specification do not contain embodiments wherein substituents X^1 , X^2 , Y,

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R², R³, R¹², R¹³, R²², and R²³ are anything other than those exemplified in examples 1 or 2 of the instant specification (pages 12 and 17).

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Correlation between Structure and Function:

A correlation between structure and function, for the instantly claimed genus of compounds, is neither known in the art nor disclosed in the specification. Thus, it is not understood what specific structural elements are essential for the optical activity of the instantly claimed compounds.

III. Analysis of Fulfillment of Written Description Requirement:

The structural/activity relationship (SAR) for binding and activity is elucidated upon analysis of IC₅₀ data of multiple compounds with various types of structural modifications. These types of studies provide insight into the structural limitations that are required for activity, i.e., specific structural elements essential for the claimed activity. In the absence of such correlation, it is not possible to determine what structural modifications will allow for the preservation of the desired activity.

In conclusion, (i) substantial structural variation exists in the genus/subgenera embraced by claims 1-3, 6, 8, and 20; (ii) disclosure of species supporting genus is limited to compounds reduced to practice, which scope is not commensurate with the scope of genus/subgenera claimed; (iii) common structural attributes of the genus/subgenera, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art.

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Thus, the specification fails to provide adequate written description for the genus of compounds claimed and does not reasonably convey to one skilled in the relevant art that the invention(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

5. Claims 1-3, 6, 8, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some compounds of the formulae of instant claim 1 does not reasonably provide enablement for all compounds of the formulae of instant claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

<u>Nature of the invention</u>: The rejected invention is drawn to a various compounds of the following formulae in which all variables are indicated within the claim.

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Relative skill of those in the art: The relative skill of those in the art is high.

Breadth of claims: The claims are extremely broad in that they encompass a large number of possible structural components for variables X^1 , X^2 , Y, R^2 , R^3 , R^{12} , R^{13} , R^{22} , and R^{23} of the compounds of formula (I).

State of the prior art/Predictability or unpredictability of the art: The skilled artisan would view that the synthesis of all possible variations of the compounds of formula (I) would require much experimentation.

Amount of guidance/Existence of working examples: More importantly, there are working examples present for only a subset of the possible variations of compounds of formula (I). Working examples are only present for the following compounds:

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No working examples are present for any other substituents of the variables claimed in instant claim 1.

Lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Thus, the specification fails to provide <u>clear and convincing evidence</u> in sufficient support for making the claimed compounds as recited in the instant claims.

Genetech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, e.g., the amount of guidance provided and the lack of working examples, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in <u>undue experimentation</u>, with no assurance of success.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belfield *et al.* [Belfield, Kevin D. Synthesis, Characterization, and Optical Properties of New-Two-Photon-Absorbing Fluorene Derivatives. *Chem. Mater.* 16 (2004) 4634-4641.] in view of Patani et al. [Patani, George A., Bioisosterism: A rational approach in drug design. *Chem. Rev.* 96 (1996) 3147-3176.]

Determination of the scope and contents of the prior art

This reference teaches obvious variants of the instantly claimed compounds.

Ascertaining the differences between prior art and the instant claims

The following compound is a bioisostere and homologue of the instantly claimed compounds of claims 1 and 8.

Belfield et al. teaches the following compound on page 4636.

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 $R = C_0 H_0$ (1), $C_{10} H_{21}$ (2)

The difference between this compound and the instantly claimed compounds is the ethyl chain at position R above, rather than the propyl chain as instantly claimed, as well as the hydrogen atoms replacing the methyl groups at positions $R^{12, 13, 22, 23}$. These are all homologous substitutions. Furthermore, there is an -H versus -OH isosteric substitution on instantly claimed position Z^1 .

Resolving the level of ordinary skill in the pertinent art - Prima Facie Case of Obviousness

Patani et al. discusses bioisosterism in conventional methods of drug design. In section II, classic bioisosteres are discussed. Furthermore, in section A4, bioisosteres which are monovalent atoms or groups are discussed, specifically, the interchange of hydroxyl groups as replacements for hydrogen atoms (Grimm's Hydride Displacement Law). On page 3152, Patani et al. discusses the interchange of –H and –OH and its recent use in the design of various drugs. Furthermore, Patani et al. details various studies in which the "increase in the effective van der Waal's radii of the isosteric substituent resulted in a decrease in activity"; however, "no significant alteration in preferential activity" occurred. "The retention of activity within a series of bioisosteres provides the basis for the discovery of a possible correlation between pharmacological activity and the physicochemical properties of specific agents."

One would be motivated, based on the disclosure of Patani et al., to replace -H with an -OH group in conventional drug design. One of ordinary skill in the pertinent art would be

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motivated to make the aforementioned modifications to arrive at compounds with similar structures for the same quoted purpose.

With regards to homologues, MPEP 2144.08.II.A.4(c) states, "...consider teachings of a preferred species within the genus. If such a species is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties."

To those skilled in the chemical art, one homologue is not an advance over an adjacent member of a homologous series. The reason for this is that one of ordinary skill, knowing the properties of one member of series, would know what properties to expect in adjacent members. Hydrogen and methyl are deemed obvious variants. Adjacent members of an alkyl chain, propyl and ethyl in the instant case, are adjacent homologues. *In re* Wood, 199 USPQ 137 (CCPA 1978), *In re* Henze, 85 USPQ 261 (1950), and *In re* Lohr, 137 USPQ 548, 549 (CCPA 1963).

One of ordinary skill would be motivated, from the exemplified embodiments in the prior art disclosure, to make the modification required to arrive at the instant invention with reasonable expectation of success for obtaining an additional compound for the same utility. The motivation would be to make additional compounds for the same quoted purpose.

Thus, the instant claims are *prima facie* obvious over the teaching of the prior art.

7. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang *et al.* [Yang, Nam C. An iodide sensory property of a strongly blue-fluorescent polycationic molecular wire from a new polybenzimidazole. *Polymer Bulletin.* 49 (2003) 371-377.] in view of

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Patani et al. [Patani, George A., Bioisosterism: A rational approach in drug design. *Chem. Rev.* 96 (1996) 3147-3176.]

Determination of the scope and contents of the prior art

This reference teaches obvious variants of the instantly claimed compounds.

Ascertaining the differences between prior art and the instant claims

The following compound is a bioisostere and homologue of the instantly claimed compounds of claims 1 and 8.

Yang et al. teaches the following compound on page 375.

The difference between this compound and the instantly claimed compounds is the pentyl chain R above, rather than the propyl chain as instantly claimed, as well as the hydrogen atoms replacing the methyl groups at positions $R^{12, 13, 22, 23}$. These are all homologous substitutions. Furthermore, there is an -H versus -OH isosteric substitution on instantly claimed position Z^1 . Resolving the level of ordinary skill in the pertinent art - Prima Facie Case of Obviousness

See section 6 above.

Conclusion

8. No claims are allowed.

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9. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-

5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

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like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/ Examiner, Art Unit 1626 /Kamal A Saeed/ Primary Examiner, Art Unit 1626